Applicant: Burrell et al Attorney's Docket No.: 14072-010001

Serial No. : 09/840,637 Filed : April 23, 2001

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REMARKS

In response to the Office Action mailed August 28, 2002, Applicants cancelled claim 4, and amended claims 1, 5, 7, 10 and 11. Applicants also added new claims 17-22. Claims 1, 3 and 5-22 are presented for examination.

The Examiner rejected claims 1 and 3-16 under 35 U.S.C. §103(a) as being unpatentable over WO 93/23092 ("Burrell I") and WO 98/41095 ("Burrell II") in view of U.S. Patent No. 4,828,832 ("DeCuellar") and CN 1291667 ("Shu"). In essence, the Examiner's reasoning appears to be that, because DeCuellar and Shu disclose that certain types of silver are effective in treating acne, one skilled in the art would have been motivated to use a different form of silver (the form of silver disclosed in Burrell I and Burrell II) to treat acne, thereby resulting in the subject matter covered by claims 1 and 3-16.

Applicants cancelled claim 4, and so the rejection on this ground should be withdrawn.

Applicants do not concede that the Examiner's characterizations of the prior art are correct. Nonetheless, assuming arguendo, that the characterizations are correct, the subject matter covered by claims 1, 3 and 5-16 is not obvious in view of the Examiner's combination of prior art.

The Examiner is reminded that the prior art must meet two criteria in order to make a claimed invention obvious. First, the prior art must suggest the invention. Second, the prior art must provide a reasonable expectation that the invention can be practiced successfully. As the United States Court of Appeals for the Federal Circuit discussed in <u>In re Vaeck</u>, 947 F.2d 488, 493 (Fed. Cir. 1991):

Where the claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under §103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill in the art would have a reasonable

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expectation of success. See In re Dow Chemical Co., 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. Id.

The prior art relied upon by the Examiner does not meet either criterion.

DeCuellar discloses that a certain type of silver, which DeCuellar believes to be silver oxide ions, is effective in treating skin lesions without causing certain undesirable side effects. (DeCuellar col. 1, line 65-col. 3, line 17). But, DeCuellar also discloses that the use of a different form of silver, which DeCuellar states to be silver ions, in the treatment of skin lesions does result in undesirable side effects. (Id. col. 1, lines 31-65). Thus, after reading DeCuellar, one skilled in the art would understand that it is difficult to predict the effectiveness of different forms of silver in the treatment of skin lesions, and that different forms of silver can provide dramatically different results, with some forms of silver possibly causing undesirable side effects. Accordingly, DeCuellar's apparent success in treating acne with a particular form of silver would not have motivated one skilled in the art to use the form of silver disclosed in Burrell II in the treatment of acne.

Similarly, Shu provides no motivation to replace his silver with the silver disclosed in Burrell I and Burrell II in the treatment of acne. At best, Shu appears to simply disclose that a particular type of silver (apparently, a silver foil) could be used to treat acne. However, as DeCuellar himself clearly demonstrates, when used to treat skin conditions, various types of silver can result in undesirable side effects. Thus, Shu's apparent success in treating acne with a particular form of silver would not have motivated one skilled in the art to use the form of silver disclosed in Burrell I and Burrell II in the treatment of acne.

Moreover, even if one skilled in the art were somehow motivated to replace DeCuellar's silver oxide ions with the form of silver disclosed in Burrell I and Burrell II in the treatment of acne, there is no basis in the prior art for a reasonable expectation that the resulting composition could be successfully used to treat, for example, acne. DeCuellar himself makes it clear that the outcome achieved by using different forms of silver to treat skin conditions is highly unpredictable.

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Likewise, even if one skilled in the art were somehow motivated to replace Shu's form of silver with the form of silver disclosed in Burrell I and Burrell II in the treatment of acne, there is no basis in the prior art for a reasonable expectation that the resulting composition could be successfully used to treat, for example, acne. This is made clear, for example, by DeCuellar, who demonstrates that the outcome achieved by using different forms of silver to treat skin conditions is highly unpredictable.

In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection of claims 1, 3 and 5-16 under 35 U.S.C. §103(a) as being unpatentable over Burrell I and Burrell II in view of DeCuellar and Shu.

The Examiner rejected claims 1 and 3 under 35 U.S.C. §102(b), or in the alternative under 35 U.S.C. §103(a), over GB Patent Specification 1 270 410 ("Lorina").

Applicants amended claim 1 to include the limitations of previously pending claim 4, which was not rejected in view of Lorina. Claim 3 depends from claim. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 1 and 3 under 35 U.S.C. §§102(b)/103(a) in view of Lorina.

Attached is a marked-up version of the changes being made by the current amendment.

Applicants believe the application is in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

(20/2002

Sean P. Daley Reg. No. 40,978

Fish & Richardson P.C. 225 Franklin Street

Boston, Massachusetts 02110-2804

Telephone: (617) 542-5070 Facsimile: (617) 542-8906

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In the claims:

Applicants cancelled claim 4, and added new claims 17-22. Applicants amended the claims as follows.

--1. (Twice Amended) A method of treating acne conditions, which comprises: contacting an acne problem area of a patient[,] with a therapeutically effective amount of one or more antimicrobial metals in a nanocrystalline form to provide a localized antimicrobial anti-inflammatory effect,

wherein:

the one or more antimicrobial metals [are characterized by] <u>have</u> sufficient atomic disorder[, such] <u>so</u> that the metal, <u>when</u> in contact with an alcohol or water-based electrolyte, releases atoms, ions, molecules, or clusters of <u>the</u> at least one antimicrobial metal <u>into the alcohol</u> <u>or water-based electrolyte</u> at a concentration sufficient to provide a localized antimicrobial and anti-inflammatory effect; <u>and</u>

the one or more antimicrobial metals are provided as a coating on, or filler in, a dressing, or in a pharmaceutical composition with one or more pharmaceutically and dermatologically acceptable carriers, diluents or excipients suitable for topical administration.

- 5. (Once Amended) The method as set forth in claim [4] 1, wherein the pharmaceutical composition includes a nanocrystalline powder of one or more antimicrobial metals, or a solution containing dissolved species from a nanocrystalline powder or coating of one or more antimicrobial metals.
- 7. (Once Amended) The method as set forth in claim [4] 1, wherein the coating is provided on a dressing.

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10. (Once Amended) The method as set forth in claim 7, wherein the [nanocrystalline antimicrobial metal] coating comprises:

a base layer of partly reflective material capable of generating an interference colour when covered with a partly reflective, partly light transmissive top layer; and

a top layer formed over said base layer, said top layer being a partly reflective, partly light transmissive thin film containing at least one noble metal <u>in nanocrystalline form</u> and having a thickness [such] <u>so</u> that a first or second order interference colour is produced, said top layer having a refractive index different from that of said base layer, and the noble metal being formed with sufficient atomic disorder [such] <u>so</u> that the top layer, in contact with an alcohol or water based electrolyte, releases ions, atoms, molecules or clusters of the noble metal into the alcohol or water based electrolyte on a sustainable basis.

11. (Once Amended) The method as set forth in claim 10, wherein the dressing is fixed in place with an occlusive or semi-occlusive layer which maintains the dressing in a moist condition.--